Initial Approval: April 10, 2019
Revised Dates: July 10, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Topiramate Extended Release

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES: Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.
Qudexy XR® (topiramate extended-release)
Trokendi XR® (topiramate extended-release)

CRITERIA FOR INITIAL APPROVAL FOR ALL PRODUCTS (DRUG-SPECIFIC CRITERIA DEFINED IN TABLE 1): (must meet all of the following)

- Medication must be prescribed for an FDA-approved indication.
- For use in migraine prophylaxis, the patient must meet the following step-therapy criteria:
  - Patient must have experienced an inadequate response after a trial (at least 6 weeks) of at least one agent from each medication class listed in Table 2 at a maximum tolerated dose, OR have a documented intolerance or contraindication to all preventive therapies.
  - Patient must have experienced an inadequate response to a trial of a botulinum toxin indicated for chronic migraines (trial of at least 180 days), OR have a documented intolerance or contraindication to treatment with botulinum toxins.[2]
  - Patient must have experienced an inadequate response to a trial of a CGRP antagonist agent listed in Table 3 (trial of at least 90 days) for chronic migraine treatment OR have a documented intolerance or contraindication to treatment to all CGRP targeted therapies.[2]
  - The patient has experienced a reduction in the number of monthly headache days compared to baseline while using topiramate immediate-release formulation.
  - Prescriber must provide documentation of all previous medication trials. Documentation must include the medication name(s), trial date(s) and outcome(s) of the trial (i.e. inadequate response, intolerance or contraindication).
- Medication must be prescribed within an FDA-approved age range, as defined in Table 1.
- Medication must be prescribed by or in consultation with a neurologist
- Dose of medication requested must be consistent with FDA-approved labeling, as defined in Table 1.

LENGTH OF APPROVAL (INITIAL): 6 months

CRITERIA FOR RENEWAL APPROVAL FOR ALL PRODUCTS (DRUG-SPECIFIC CRITERIA DEFINED IN TABLE 1): (must meet all of the following)

- The patient has experienced a significant reduction in the number of monthly headache days compared to previous treatment with the topiramate-immediate release formulation.
- The patient has experienced a reduction in the number of monthly headache days of at least moderate severity compared to baseline.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL: 12 months

References

1. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders,3rd edition. Cephalalgia. 2018;38:1-211. Available at https://ichd-3.org/. Accessed 6/19/19.
2. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache 2019;59:1-18. Available at https://americanheadachesociety.org/resources/guidelines/guidelines-position-statements-evidence-assessments-and-consensus-opinions/. Accessed on 6/19/19.
3. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78:1337-45. Available at https://www.aan.com/Guidelines/home/GuidelineDetail/536. Accessed 6/18/19.
4. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology 2016; 86 (19): 1818-26. Available at https://www.aan.com/Guidelines/home/GuidelineDetail/735. Accessed 6/18/19.

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE

DATE

TABLE 1. MEDICATION-SPECIFIC CRITERIA

INDICATION	MEDICATION	AGE (years)	DOSING LIMIT
Lennox-Gastaut Syndrome (LGS)	Qudexy XR	≥ 2	400 mg daily
	Trokendi XR	≥ 6	400 mg daily
Migraine Prophylaxis	Qudexy XR	≥ 12	100 mg daily
	Trokendi XR	≥ 12	100 mg daily
Partial Onset Seizures	Qudexy XR	≥ 2	400 mg daily
	Trokendi XR	≥ 6	400 mg daily
Primary Generalized Tonic-Clonic Seizures	Qudexy XR	≥ 2	400 mg daily
	Trokendi XR	≥ 6	400 mg daily

TABLE 2. PRIOR PREVENTATIVE MIGRAINE THERAPIES

BETA-BLOCKING AGENTS	ANTIEPILEPTIC AGENTS
Propranolol	Topiramate
Metoprolol	Valproic acid
Timolol	Divalproex

TABLE 3. CGRP-TARGETED MIGRAINE PROPHYLAXIS THERAPIES

CGRP-TARGETED THERAPIES
Erenumab-aooe (Aimovig™)
Fremanezumab-vfrm (Ajovy™)
Galcanezumab-gnlm (Emgality™)